CHEMICAL HAZARD DATA AVAILABILITY STUDY

What Do We Really Know About the Safety of High Production Volume Chemicals?

EPA's 1998 Baseline of Hazard Information that is Readily Available to the Public

Prepared by EPA's Office of Pollution Prevention and Toxics (April 1998)

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This report presents the results of EPA's analysis of test data availability for 2,863 organic chemicals produced or imported at or above 1 million pounds per year in the United States. The report includes a chemical-by-chemical presentation of the hazard information available to the public on each of the US High Production Volume (HPV) chemicals.

The US produces or imports close to 3,000 chemicals (excluding polymers and inorganic chemicals) at over 1 million pounds per year. A fundamental question concerns whether, and to what extent, basic toxicity information is available to the public on these major commercial chemicals in the United States. One might assume that basic toxicity information is available for these chemicals so that producers, users, workers, and consumers could be aware and be able to evaluate the hazards and risks posed by the chemicals they encounter in their daily lives. Based on results from a recent analysis done by EPA, this is not a prudent assumption. **EPA's analysis found that *no basic toxicity information, i.e., neither human health nor environmental toxicity, is publicly available for 43% of the high volume chemicals manufactured in the US and that a full set of basic toxicity information is available for only 7% of these chemicals.***

The lack of availability of basic toxicity information on most high volume chemicals is a serious issue for several reasons. For EPA, the availability of hazard information on individual chemicals is fundamental to many of the Agency's approaches to accomplishing its mission of environmental protection -- risk assessment, safeguarding children's health, expanding the public's right-to-know, and promoting the pollution prevention ethic. Long-range strategic planning at EPA has recently been formalized and expanded as a result of the Agency-wide effort to implement the Government Performance and Results Act (GPRA) of 1993. Strategic program objectives under the Toxic Substances Control Act (TSCA) for EPA's Office of Pesticides, Prevention, and Toxic Substances, incorporated into the Agency-wide strategic plan, call for EPA to significantly increase the introduction by industry of safer or "greener" chemicals which will decrease the need for regulatory management by EPA, and to improve the ability of the public to reduce exposure to specific environmental and human health risks by making current, accurate substance-specific information widely and easily accessible. Steps to ensure the availability of basic toxicity information on HPV chemicals would be an integral part of meeting these objectives.

Congress acknowledged the need for data in identifying, controlling and preventing the possible hazardous effects of chemicals on health and the environment when it passed TSCA (P.L. 94-469, October 11, 1976). TSCA states that it is the policy of the US that manufacturers are responsible for testing chemicals, and the Act gives EPA some authority to require chemical testing and impose controls as necessary. In practice, implementation has been difficult for a variety of reasons and the rate of testing has been slow. It is time to fill the gap in information about these high volume chemicals. US companies need to do much more testing and generate basic toxicity assessments in a form that is publicly available and usable by consumers, community groups, chemical users, and workers. Industry has committed to increase testing, but their progress has been slow; meanwhile companies continue to reap significant profits from the production and sale of these HPV chemicals.

What Tests are Necessary?

International authorities agree that testing in six basic endpoint areas (known as "basic tests" in this report) is necessary for a minimum understanding of a chemical's toxicity. These tests cover: acute toxicity; chronic toxicity; developmental and reproductive toxicity; mutagenicity; ecotoxicity; and environmental fate. This basic level of testing and other information is called the Screening Information Data Set, or SIDS. The SIDS includes information on the identity of the chemical, its physical and chemical properties, uses, sources and extent of

exposure. The testing required is designed to answer basic questions about the chemical. For instance, environmental fate testing can indicate whether the chemical degrades quickly in the environment and how it is distributed throughout the environment. Acute toxicity testing is designed to measure how toxic the chemical is from acute or one-time exposures, such as from accidental ingestion or skin contact. Other tests measure the effects from longer exposures as might be encountered in the workplace or in communities near production facilities, such as subchronic toxicity testing and mutagenicity tests (which could indicate a potential to cause cancer). Tests are also required that measure the chemical's ability to interfere with reproduction (fertility) and fetal development. Finally, a number of studies are required to indicate the potential for environmental effects such as to fish, invertebrates, and aquatic plants should the chemical be released to water from production and wastewater treatment facilities. While these tests do not fully measure a chemical's toxicity, they do provide a minimum set of information that can be used to determine the relative hazards of chemicals and to judge if additional testing is necessary.

Background

While there is much work to be done, it is true that some progress has been made in improving our understanding of chemical hazards and risks in the past twenty years. The National Academy of Sciences National Research Council (NAS/NRC, 1984) studied this question in the mid-1980s and concluded that "minimal" toxicity information was available for only 22% of high volume chemicals.[1] The Organization for Economic Cooperation and Development (OECD), recognizing this problem in the late 1980s, initiated a voluntary program to assure that basic information is available on international high production volume (HPV) chemicals (OECD, 1990). This program, known as the Screening Information Data Set or SIDS program, has produced an internationally-agreed-upon set of screening tests[2] and is working to complete the SIDS data set for international HPV chemicals (OECD, 1998a). To date, the OECD has initiated or completed work on over 300 HPV chemicals (OECD, 1998b). The US has committed to handling 25% of the HPV chemicals as its contribution to the OECD SIDS effort; other countries have committed to handling chemicals in proportion to the size of their gross domestic product. Because most of the international HPV chemicals are also commercially available in the US, EPA considers the OECD/SIDS program to be an integral part of domestic testing activities. EPA has committed to partnering with industry in the US and abroad to achieve the common goal of accomplishing this minimum level of testing for HPV chemicals and will work with other parties (international organizations, environmental groups, unions, other Federal agencies, environmental justice groups and others) to secure their interest and support for this effort. Nevertheless, because of the slow pace of the international efforts to generate the needed data, it will be necessary for the US to accelerate its efforts in order to ensure the availability of the data needed to support US domestic efforts on chemicals.

Last year, the Environmental Defense Fund (EDF, 1997) reported in "Toxic Ignorance" the results of its analysis of the availability of basic health test data on HPV chemicals and concluded that only 29% of the HPV chemicals in the US met the minimum data requirements for health hazard screening established by the OECD/SIDS program. Note that the percentages reported in EDF's conclusions were based on a selected sample of 100 HPV chemicals, and deal only with human health hazard information, which is a subset of the full SIDS described above. EDF subsequently challenged the US chemical industry to confront this issue and

[1] The National Research Council defined "minimal toxicity information" for industrial chemicals as the availability of any one or more of the five test types included in their study: acute toxicity; subchronic toxicity; chronic toxicity; reproductive/developmental toxicity; mutagenicity.

[2] The OECD Screening Information Data Set consists of the following required tests:
Physical/Chemical Properties - melting/boiling point; water solubility; vapor pressure; octanol/water partition coefficient; water solubility.
Environmental Fate - aerobic biodegradation.
Environmental Toxicity - acute toxicity to fish, Daphnia, and algae.
Toxicological Data - acute toxicity; repeated dose toxicity; genetic toxicity; reproductive/developmental toxicity.

accept the responsibility for assuring completion of and public access to health screening test data on HPV chemicals.

The Chemical Manufacturers Association (CMA) conducted its own analysis of the sample of 100 HPV chemicals and concluded that 47% of the chemicals had full SIDS health data sets - a conclusion which, although quantitatively different from EDF's, is consistent with the view that significant basic testing requirements remain to be filled for the HPV chemicals.

With regard to industry response to the EDF challenge, CMA, its member companies, and others in the US chemical industry have expressed an interest and willingness to engage both EDF and EPA in a constructive dialogue to address the significant issues raised in the "Toxic Ignorance" report. CMA, on behalf of its member companies, previously agreed to the policy adopted by the OECD that high production volume status alone is sufficient to establish the need for a full SIDS data set. Unfortunately, there is a major inconsistency between CMA's Responsible Care/Product Stewardship Program and the organization's written commitment to the OECD/SIDS program in that the Responsible Care/Product Stewardship codes do not include a commitment to ensure that SIDS data sets are developed and made publicly available for HPV chemicals. Recent developments indicate that CMA is considering a number of initiatives to increase industry participation in SIDS testing, including increasing its voluntary commitment to the SIDS program. CMA has also initiated an expansive search effort to determine the actual amounts and types of SIDS data which are available for HPV chemicals. These are encouraging signs, but must be followed by concrete actions.

EPA concluded that a comprehensive analysis looking at the full set of US HPV chemicals was needed to determine the public availability of basic screening data on these chemicals. This baseline report is the result of that analysis, and should clarify the magnitude of the problem and establish a basis against which future improvements can be judged. EPA intends to update this search periodically to measure progress against these initial baseline results.

EPA recognized the importance of and welcomed EDF's evaluation and its challenge to the chemical industry on this critical issue. While the EDF report's challenge to US industry focuses on human health-related information, EPA believes that the full SIDS data set (which includes environmental fate and effects information) is needed. EPA applauds the willingness of both EDF and CMA to join in this "constructive discussion" and the Agency welcomes strong participation from other environmental groups and a broader range of stakeholders. It is encouraging that these major organizations are in agreement with the basic message that more testing is needed.

Method

The evaluation of the availability of hazard data for US HPV chemicals included a search for basic health and environmental information on these chemicals, as well as a comparison of available information for various subsets of the 3,000 HPV chemicals. Important aspects to the current methodology include:

1. The search for available hazard data was restricted to information in the Chemical Information System (CIS, 1998).

2. Assessment of various subsets of chemicals (such as Toxic Release Inventory chemicals, or chemicals with an associated Occupational Health and Safety Administration Permissible Exposure Limit) are based only on the subset of those chemicals identified as HPV.

3. The analysis focused on identifying "publicly available" data on these HPV chemicals. EPA considered "publicly available" data as meeting the following requirements: that full descriptions of the study method and the results obtained were accessible to the public. The data can exist in the form of a journal article or as a publicly accessible study report such as a study submitted to EPA under section 4 or sections 8(d)/8(e) of TSCA. EPA recognized that

while various publicly accessible databases point to the existence of test data (in the form of brief data summaries), the studies cited in these data bases *do not* meet the requirement that "full descriptions of the study method and the results obtained" were publicly accessible and thus have not been included in this analysis.[3]

Creation of the US HPV Hazard Database

A database containing the results of a search for available hazard data on US HPV chemicals (excluding polymers and inorganics) was created for use in this analysis. These chemicals are restricted to those for which data were submitted to EPA under the 1990 TSCA Inventory Update Rule. TSCA chemicals do not include cosmetics, drugs, food and food additives, pesticides, nuclear material, firearms, tobacco and tobacco products. A brief description of the format of this database is provided in Appendix I. The database will soon be available on EPA's Chemical Testing and Information High Production Volume website at www.epa.gov/opptintr/chemtest/hpv.htm.

An extensive search for all publicly available hazard data was not conducted due to limited resources; thus, the search was restricted to information in the Chemical Information System (CIS). It is noted that the search strategy used in this study is not comprehensive and will have missed studies that were not included in the data bases searched. Studies contained in databases which did not meet the criteria for "publicly available" data, such that full descriptions of the study method and results obtained were available to the public, have also been excluded from the analysis.

The CIS was originally formed under joint contract to EPA and NIH, and is a publicly accessible commercial vendor for nearly 100 databases. Among its varied topics, the CIS includes a number of different source collections and datasets which document available data related to the SIDS test battery which served as the basis for evaluating chemicals in these analyses. As noted, the six endpoints comprising the SIDS test battery are acute toxicity, chronic toxicity, developmental and reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate. Details of the CIS search are presented below.

The Chemical Abstract Services (CAS) registry numbers for the approximately 3,000 HPV chemicals were used to search the CIS databases. CAS numbers, as opposed to chemical names, were used as a matching criteria because CAS numbers are uniquely assigned to chemicals, while chemicals are often known by multiple names.

In addition to its multiple individual data sources which can be searched, the CIS contains a separate system, known as the Structure and Nomenclature Search System (SANSS), that can be used to identify which of the individual data sources contain information for a particular chemical. Although the SANSS is an easier way to identify available information across all of the individual data sources, it is not updated as frequently as the individual data sources. For this reason, some of the individual data sources (RTECS, TSCATS, IRIS, GENETOX, AQUIRE, Phytotox, and Envirofate) were searched independently of the search that was performed using SANSS. The eleven CIS-SANSS data sources which were used in the search for available hazard data are listed below. Descriptions of each of the data sources are presented in Appendix II.

- Registry of Toxic Effects of Chemical Substances (RTECS)
- Toxic Substances Control Act Test Submissions (TSCATS)
- Integrated Risk Information System (IRIS)
- Chemical Carcinogenesis Research Information System (CCRIS)
- GENETOX

[3] One example can be found in a paper prepared by the Chemical Manufacturers Association (CMA, 1997) which included EUCLID, a data base prepared by the European Union. In many instances, the information which is available on studies included in EUCLID is limited to the summary provided in the database, thus additional documentation as to the study method and details on the results is not publicly available for many of the studies.

- Environmental Mutagen Information Center (EMIC)
- Environmental Teratology Information Center (ETIC)
- Catalog of Teratogenic Agents (CTA)
- Aquatic Information Retrieval Database (AQUIRE)
- Phytotox
- Envirofate

For each SIDS endpoint, Table A lists the individual data sources which were searched, along with the specific keywords used, where applicable.

Table A. Individual Data Sources Searched for Available Hazard Data on Each SIDS Test Component

SIDS Test Component	Data Source	Search Keyword
Acute Toxicity	RTECS TSCATS	TOX HE-ATOX
Chronic Toxicity	TSCATS IRIS	HE-CTOX HAZ (RfD)
Developmental & Reproductive Toxicity	RTECS TSCATS ETIC CTA	TER HE-RTOX-TERA
Mutagenicity	RTECS TSCATS GENETOX EMIC	MUT HE-GTOX
Ecotoxicity	AQUIRE TSCATS Phytotox	EE-ATOX, EE-CTOX, EE-RTOX
Environmental Fate	TSCATS Envirofate	EF

This analysis focused on a Abest case@ scenario in that credit for data availability was given to several endpoints even though the complete SIDS testing requirement for that endpoint may not be met. Specifically, for reproductive/developmental toxicity, mutagenicity, ecotoxicity, and environmental fate tests, the analysis accepted the availability of at least one test in each endpoint area as being sufficient to suggest that the SIDS need was filled (in fact, multiple tests are required to fulfill the SIDS test requirements for these endpoints). In addition, no assessment of data quality was made for the data located in the various searches. The mere existence of data meeting the publicly available requirements warranted an AX@ in the column for an endpoint. Thus, the analysis only points to the availability of information.

What Basic Screening and Testing Has Been Done: Overview of Results

Tables/Figures 1 and 2 presented in Appendix III provide highlights from the analysis of US HPV chemicals to determine the availability of key test data. Examination of these tables and figures leads to the following observations: ***43% of the US HPV chemicals (1,216 of 2,863) are identified as having no SIDS test data (i.e., no basic screening data) of any type available and only 7% of the chemicals (202 of 2,863) are reported as having data available for all of the SIDS data types.*** **These statistics indicate that there are *many US HPV chemicals for which numerous SIDS data gaps exist and that there is a continuing need for significantly expanded testing efforts by US***

chemical companies to deal with this important problem.

Some 277 of the 2,863 U.S. HPV chemicals are part of the ongoing OECD SIDS international testing program, in which companies in various countries around the world have voluntarily agreed to conduct the SIDS battery of tests on selected chemicals. Most of the OECD SIDS test data are not yet publicly available, but they will become accessible as they are incorporated into existing databases. Some 46 of the 277 U.S. HPV chemicals have already completed the SIDS test battery under the OECD program. For 9 of those chemicals, all of the test data are publicly available (and are included in the counts listed in Table 2); for the remaining 37 completed chemicals, one or more of the tests, while complete, are not yet available through the publicly accessible databases searched in this study. Adding these 37 chemicals to the number of chemicals for which all SIDS data are available (202 chemicals) increases the percentage of fully-tested chemicals from 7.1% to 8.3%.

Comparisons to Other Studies

The National Academy of Sciences National Research Council (NAS/NRC, 1984) studied the availability of "minimal toxicity information" for existing chemicals in the TSCA inventory in the mid-1980s. NRC defined "minimal toxicity information" for industrial chemicals as the availability of any one or more of the five test types included in their study. The first column of Table 3 shows the availability of hazard data information for 259 US HPV chemicals based on the analysis conducted by NAS/NRC in 1984. This information was extracted from Auer and Gould (1987). NRC concluded that one of five toxicity tests (acute toxicity, subchronic toxicity, chronic toxicity, reproductive/developmental toxicity, and mutagenicity) was available for only 22% of the randomly selected set of 259 HPV chemicals. In contrast, EPA's current analysis located at least one of the human health hazard data components for 55% of the 2,863 HPV chemicals. A more direct comparison can be made by comparing the percent of chemicals with test data for a specific hazard endpoint. For instance, NAS/NRC located information on acute toxicity for only 20% of the 259 HPV chemicals. In contrast, EPA's current study was able to find test data on acute toxicity for almost 50 percent of the 2,863 HPV chemicals.

In 1997, the Environmental Defense Fund (EDF) reported in "Toxic Ignorance" (EDF, 1997) the results of its analysis of the availability of basic human health test data on a sample of 100 HPV chemicals. The Chemical Manufacturers Association (CMA, 1997) conducted its own analysis of these same 100 HPV chemicals to determine whether there are additional publicly available data which were not reflected in the EDF report. Their results of these analyses on the EDF 100 HPV chemicals and EPA's analysis results on the 2863 HPV chemicals are summarized in Table 3.

EDF's analysis estimated that only 29% of the 100 HPV chemicals met the minimum data requirements for health hazard screening established by the OECD/SIDS program. On the other hand, CMA concluded that 47% of the chemicals had full SIDS health data available. EPA's analysis estimated that only 9% of all 2863 US HPV chemicals met the data availability requirements for human health hazard screening.

EPA's investigation of the extent to which hazard data is available for the nearly 3000 US HPV chemicals is proceeding. However, the results to date indicate that significant and serious data gaps do exist related to the availability of hazard information for many of the chemicals most widely used in the United States. An examination of Table 3 indicates that while the conclusions of previous studies and EPA's current assessment are quantitatively different, they are consistent with the view that significant basic testing requirements remain to be filled for the HPV chemicals. Table 3 also indicates that this remains true even though the amount of hazard information that is publicly available for US HPV chemicals has substantially increased in the past decade.

HPV Chemicals and Right-to-Know -- What Information is Readily Available to Communities?

Test Data Availability of Selected Chemicals in the Toxic Release Inventory TRI Database

The Toxic Release Inventory (TRI), initiated by EPA in 1987, provides information to the public on releases and other waste management information for more than 600 chemicals and chemical categories from certain industry sectors. Facilities report their TRI information annually to EPA. The information includes: the amounts of each listed chemical released to the environment at the facility; amounts of each chemical shipped offsite for recycling, energy recovery, treatment, or disposal; amounts of each chemical recycled or burned for energy recovery, or treated at the facility; and maximum amounts of the chemical present at the facility during the year. With this information, communities know what toxic chemicals are present in their neighborhoods, and facility managers can identify opportunities for materials management, source reduction, pollution prevention, and cost savings.

A search of the HPV chemicals included in the 1995 Toxic Release Inventory (TRI) was conducted to determine what SIDS testing information was publicly available for these chemicals. As shown in Table 4 and Figure 3, 203 HPV chemicals appear on the TRI list. As a result of its review, EPA has learned that many chemicals may have never been tested to determine how toxic they are to humans or the environment. (A number of these chemicals are also pesticides, but, this analysis did not consider information developed under the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA)).

While one might expect TRI chemicals to be relatively well tested, in fact, there are numerous testing gaps. The subset of 203 HPV chemicals in the 1995 TRI list yielded better results than for HPV chemicals as a whole -- the full six-test SIDS battery was available for ~ 54% of the chemicals and all of the TRI HPV chemicals had at least some data available. Nonetheless, the TRI chemicals showed some significant gaps in the basic data set -- about 20% of the TRI HPV chemicals were missing 2 or more of the basic SIDS tests.

On the other hand, however, is the observation that the majority of HPV chemicals not listed on TRI lack the basic information needed to determine whether they should be listed on TRI. For example, ~ 46% of the non-TRI HPV chemicals have no data available and less than 4% have the full set of basic tests.

The HPV TRI chemicals with higher exposure potential were also examined and 91 (out of the 203) HPV TRI chemicals were identified with reported total (on-site and off-site) releases at levels greater than 1 million pounds (for the 1995 reporting year). Of these 91 high release HPV TRI chemicals, 74% have information available on all six basic SIDS tests, an additional 20% had five of the SIDS tests available, and all of the high release HPV TRI chemicals have data available from at least three of the SIDS tests. See Table 5 and Figure 4 in Appendix III. Nonetheless, given the large releases and potential for exposure, it is clear that testing beyond the basic SIDS level is necessary to adequately understand the risks of such high exposure chemicals.

HPV Chemicals and Worker Safety

Test Data Availability of Chemicals with Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits

The Federal Occupational Safety and Health Administration (OSHA) sets Permissible Exposure Limits (PELs) for hazardous chemicals in the workplace. These PELs are limits, usually calculated on an eight hour time weighted average basis, on inhalation exposures developed to protect worker health. As another means of evaluating the US HPV chemicals, EPA obtained an electronic file of the 738 chemicals currently subject to occupational exposure controls set by OSHA. Based on information in this file, EPA identified the US HPV chemicals which have OSHA PELs.

Up to six separate measures of permissible exposure limits were defined in the file. These measures were: control limit PEL in mg/m^3, control limit PEL in ppm, time weighted average PEL in mg/m^3, time weighted average PEL in ppm, short term exposure limit PEL in mg/m^3, or short term exposure limit PEL in ppm. For the purposes of this evaluation, a chemical was considered to have an OSHA PEL if any of the six limits were defined. Among the 738 chemicals in the file, 288 chemicals were excluded from the analysis because they did not have defined OSHA PELs. Of the 450 chemicals with OSHA PELs, 17 chemicals did not have CAS numbers and were also excluded from the analysis. After cross-referencing the remaining 433 OSHA PEL chemicals with the US HPV list, 193 of them were found to be high production volume chemicals. EPA assessed the extent to which hazard data are publicly available for these 193 HPV OSHA PEL chemicals as compared with the remainder of the US HPV chemicals.

The results of human health hazard data availability for OSHA PEL chemicals are summarized in Table 6 and Figure 5. EPA found that only 52% of these HPV chemicals with PELs have basic screening tests for all four of the human health endpoints (acute toxicity, chronic toxicity, developmental/reproductive toxicity, and mutagenicity). In contrast, of the HPV chemicals *without* PALS, only 5% had all four health data types and 49% had no data of any type available; more than 80% have hazard data available on two or fewer SIDS health data components. Thus, it is clear that the bulk of HPV chemicals without PELs lack even the minimal test data needed to support development of a PEL value to protect workers.

HPV Chemicals and Widely-Used Consumer Products

Test Data Availability of Chemicals Believed to be Contained in Consumer Products

Of particular interest are the statistics showing the degree to which untested chemicals are used in everyday consumer products found in the average American home. Another major concern is the range of uses and the volumes of HPV chemicals present in the materials used in construction of the homes, schools, churches, offices, factories, shopping malls, and other buildings in which Americans spend most of their time. The point here is not to identify specific brands or manufacturers; the point is that many generic product types found in every home contain chemicals that are untested for toxicity.

EPA is developing the source ranking database (S.D.) which among other things identifies the sources of consumer product chemicals (CPC). There are 1418 chemicals in the S.D., of which 1303 have unique CAS numbers. Among these 1303 chemicals, 491 are US HPV chemicals. EPA assessed the extent to which hazard data are publicly available for the 491 US HPV-CPC chemicals found in the S.D..

The results of hazard data availability for these consumer product chemicals are summarized in Table 7 and Figure 6. As the figures indicate, relative to other subsets of chemicals, substances used in consumer products appear to have received a greater level of screening testing than is typical for all HPV chemicals. However, chemicals used in consumer products warrant a higher level of testing than that provided by the SIDS set in order to adequately assess potential risks. As with the high release TRI chemicals, there is high exposure potential to chemicals in consumer products, including exposure to children. Significantly greater amounts of testing are needed to demonstrate the safety of such consumer chemicals given the large and varied makeup of the exposed population.

Do Chemical Manufacturers Ensure that Test Data are Made Publicly Available on the Chemicals They Make?

Analyses were also conducted to determine the proportion of hazard data available for US high production volume (HPV) chemicals for each manufacturer/importer of these chemicals. The analysis focused on the six basic tests previously identified to comprise a minimally acceptable screening information data set (SIDS) and, for each HPV chemical, the fraction of the six components of hazard information for which data were available was computed. For example, a given chemical might have hazard data available for only acute toxicity and ecotoxicity. This chemical has available information for two of the six hazard data components and the proportion of hazard data available for this chemical is 2/6.

For each company, the average proportion of hazard data available for all of the HPV chemicals manufactured by that company was computed. For example, suppose that a chemical company manufactures four chemicals and that the number of hazard data components available for the four chemicals are 1, 2, 0, and 3. The average proportion of the six hazard data components available for the four chemicals manufactured by that company is (1/6 + 2/6 + 0/6 + 3/6)/4 = 1/4. The average proportion is 1 if all six hazard components are available for each HPV chemical produced/imported by the company and is 0 if none of the components are available for any of the chemicals produced/imported by the company.

The results of the analysis are summarized in Figure 7. Average proportions of hazard data available ranged from 0 to 1 (6/6). For graphical purposes, the average proportions were grouped into seven categories: 0/6; > 0/6 -- < 1.5/6; 1.5/6 -- < 2.5/6; 2.5/6 -- < 3.5/6; 3.5/6 -- < 4.5/6; 4.5/6 -- < 6/6, and 6/6. The first category includes only those companies that manufacture/import chemicals that do not have any hazard data publicly available. The second through sixth categories include companies for which the average proportion of hazard data available falls within the ranges indicated. These categories include companies that manufacture just one HPV chemical whose data availability proportion fell into one of the ranges to companies that manufacture hundreds of chemicals where the average proportion of hazard data available for chemicals manufactured/imported by the company fell into a given range. The seventh category includes those companies that manufacture/import chemicals for which all hazard data are publicly available.

The analysis covered 830 manufacturers/importers of US HPV chemicals. As illustrated in Figure 7, all of the chemicals manufactured/imported by 148 of the 830 (18%) companies have no SIDS data available (i.e., 0/6 SIDS tests are available). This category is comprised of fewer than 250 chemicals. An additional 459 companies (55%) sell products for which, on average, half (3/6) or less of the SIDS tests are publicly available. Finally, for only 21 of the 830 (3%) companies can it be said that all six of the SIDS tests (6/6) are publicly available for all of their chemicals (fewer than 40 chemicals comprise this category).

The Bottom Line -- How Much Will it Cost to Get the Remaining Basic Information?

The Cost of the SIDS Screening Tests And the Profitability of HPVCs

Any additional testing or screening of chemicals has a price tag. For each chemical, the basic set of six SIDS screening test endpoints costs about $205,000. Assuming that (1) test data identified in this study as publicly available meet minimum criteria as to quality and usability and (2) where multiple studies are needed to complete an endpoint (i.e., mutagenicity, reproductive/ developmental toxicity, ecotoxicity, and environmental fate), all such studies were in fact available, Table 8 shows the estimated testing costs to complete remaining SIDS testing for all HPV chemicals. (Test data which may currently exist in restricted access files but is subsequently made publicly available would serve to lower these costs.) ***It would cost the chemical industry approximately 0.2% of the total annual***

sales of the top 100 US chemical companies to fill all of the basic screening set data gaps for the high production volume chemicals. This represents less than $427 million of the 1996 industry sales figure of $231 billion (Chemical and Engineering News, May 1997).

EPA believes, however, that for many of these chemicals, the SIDS battery of tests will not provide sufficient understanding to adequately assess the hazards and risks presented by some chemicals. Table 8 presents the specific higher tier tests that may be necessary to adequately assess the hazards of higher exposure chemicals (e.g., chemicals in consumer products, chemicals to which children may be exposed, high release TRI chemicals, chemicals with large numbers of exposed workers, etc.) and the costs for those tests. Where high exposure was not a major concern, the results of the SIDS battery of tests (identified as "Level 1 (SIDS)" tier) would be used to determine which of the assays outlined in the SIDS+ and SIDS++ batteries are a priority such that higher level testing is necessary.

Next steps

EPA plans to use the results of this analysis to establish a baseline of available testing and measure progress in generating missing needed test data against that baseline. This report will also be of value to improving company product stewardship efforts, such as CMA's Responsible Care program, because of the fundamental issues which it poses concerning implementation of effective product stewardship efforts in the absence of even basic information on chemical hazards and risks.

With this baseline report as a point of departure, EPA is gathering additional information to begin to engage manufacturers, interest groups, other Federal agencies, and academia in an effort to set priorities for completing the SIDS tests for the remaining HPV chemicals and to set goals for an aggressive testing program that will produce the hazard information on these chemicals which is needed by the public, industry, and others. For example, EPA could establish a challenge program for the industry to produce this testing by the end of 2003 or 2005. That would make the cost to industry between $61-85 million per year - representing approximately 0.04% of the chemical industry's annual sales. Considering that there are about 260 million American citizens, using the 2005 end date, that would amount to less than a quarter per year for each citizen over the seven years of testing.

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APPENDIX I.

HPV Hazard Database: Description of Database Format

The U.S. High Production Volume (HPV) chemicals database contains information on whether or not eight hazard data components are publicly available for 2931 U.S. HPV chemicals. Six of the hazard data components (acute toxicity, chronic toxicity, developmental and reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate) comprise the "Screening Information Data Set" (SIDS) test battery established by the Organization for Economic Cooperation and Development (OECD, 1998a).

Variable names for each column are shown in the first row. The remaining rows contain the information on hazard data availability for the chemicals. The first column (CAS) contains a chemical identity number: Chemical Abstract Services registry number. CAS numbers are uniquely assigned to chemicals. The name of the chemical is displayed in the second column (CHEMNAME). An "X" is shown in the third column (ACUTE), if EPA was able to locate any information on acute toxicity testing. Columns 4 (CHRONIC), 5 (DEVEL/REPRO), 6 (MUTAGEN), 7 (ECOTOX), and 8 (FATE) are also marked with an "X" if hazard data were located for chronic toxicity, neurotoxicity, developmental/reproductive toxicity, mutagenicity, carcinogenicity, ecotoxicity, and environmental fate, respectively. The total number of eight hazard data test components located for each chemical is shown in Column 9 (TOTAL).

Some 277 of the 2931 U.S. HPV Chemicals are part of the ongoing OECD SIDS international program. Some of the OECD SIDS test data have not been entered into the databases searched in this study. The database will be updated to include that information once the hazard data become available. A "C" or "U" is marked in Column 10 (SIDS) if the chemical is part of SIDS testing program. A "C" indicates that testing has been completed, and a "U" denotes that testing is ongoing. Copies of completed SIDS dossiers are available through the United Nations Environmental Programme (UNEP, 1996).

The table below displays the information contained in the database for three sample chemicals. The CAS number and chemical name of the first chemical are 71432 and benzene. As shown below, all six hazard tests have been conducted for benzene, and the chemical is active under the SIDS program . On the other hand, only three of the hazard tests (acute toxicity, ecotoxicity, and environmental fate) were located for hexene (CAS no. 25264931), and none of the six were located for 1-octanesulfonyl fluoride (CAS no. 40630635).

This database will be available at EPA's Chemical Testing and Information High Production Volume website at www.epa.gov/opptintr/chemtest/hpv.htm.

CASNO	CHEMNAME	ACUTE	CHRONIC	DEVEL/ REPRO	MUTAGEN	ECOTOX	FATE	TOTAL	SIDS
71432	Benzene	X	X	X	X	X	X	6	U
25264931	Hexene	X				X	X	3	
40630635	1-Octanesulfonyl fluoride							0	

APPENDIX II.

Where can the Public Find the Information?: Selected Data Sources

Data Sources Available through the Chemical Information System (CIS)
-- Call 1-800-247-8737 for information on CIS.

1. Registry of Toxic Effects of Chemical Substances (RTECS): RTECS is a comprehensive database of basic toxicity information for over 100,000 chemical substances. It is maintained by NIOSH, and contains quarterly updates from 1971 to present. In addition to toxic effects and general toxicology reviews, data on skin and/or eye irritation, mutation, reproductive consequences, and tumorigenicity are provided. Toxic effects are linked to literature citations from both published and unpublished government reports (including unpublished test data from TSCATS, the EPA TSCA test submissions database), and published articles from the scientific literature. The database can also be searched online through the TOXNET system. URL: http://sis.nlm.nih.gov

2. Toxic Substances Control Act Test Submissions (TSCATS): TSCATS is a database that indexes unpublished health and safety studies, chemical test data, and substantial risk data submitted to EPA under TSCA sections 4, 8(d), 8(e), and "For Your Information" ("FYI"). It was developed by Syracuse Research Corporation for EPA's Office of Toxic Substances, and is a means of conveying the Agency's receipt of unpublished, non-confidential studies covering test results and adverse effects of chemicals on health and ecological systems submitted under TSCA. TSCATS catalogs the purpose of testing (observations sought), the test organisms used, the routes of administration, and, where available, a description of the nature of the chemical tested (e.g., pure, component of a mixture). The title of the submission is given, as well as file identification data. The database can also be searched online through the NLM Medlars system. URL: http://sis.nlm.nih.gov

3. Integrated Risk Information System (IRIS): IRIS, prepared and maintained by EPA, is an electronic database containing health risk and EPA regulatory information on specific chemicals. IRIS was developed by EPA staff in response to a growing demand for consistent risk information on chemical substances for use in decision-making and regulatory activities. IRIS is designed for EPA staff, but is also accessible to state and local environmental health agencies. The information in IRIS is intended for individuals with extensive training in toxicology, but with some knowledge of health sciences. The database can also be searched online through the TOXNET system. URL: http://sis.nlm.nih.gov

4. Chemical Carcinogenesis Research Information System (CCRIS): CCRIS contains over 7,300 chemical records and is sponsored by the National Cancer Institute. It contains scientifically evaluated data derived from carcinogenicity, mutagenicity, tumor promotion, and tumor inhibition studies. The database can also be searched online through the TOXNET system. URL: http://sis.nlm.nih.gov

5. GENETOX: GENETOX is a collection of genetic assay studies developed through the collaborative efforts of the National Institute of Environmental Health Sciences, the Oak Ridge National Laboratory, and the Environmental Mutagen Information Center (EMIC). The database is directed toward the goal of establishing standard genetic testing and evaluation procedures for the purposes of regulating toxic substances and determining the direction of research and development in this area. Assays are compared on a chemical-by- chemical basis. Each GENETOX record corresponds to an individual chemical and may incorporate several studies. Assay results are included on mutagenicity tables. These tables provide specific information on the type of assay, the biological host, the assay endpoint, and the final qualitative results of the assay. When available, reference information for the assays is also given.

GENETOX data are derived from the results of assays selected from published primary papers and from reports submitted to EMIC from contractors. Chemical data included in the database comes from the following sources: EMIC (Environmental Mutagen Information Center), ETIC (Environmental Teratogen Information Center), SOLM, WATER POLLUTION, OSHA (Occupational Safety and Health Administration), CHEMLINE, TSCA (Toxic Substances Control Act) Lists, and RTECS (Registry of Toxic Effects of Chemical Substances). The database can also be searched online through the TOXNET system. URL: http://sis.nlm.nih.gov

6. Aquatic Information Retrieval Database (AQUIRE): AQUIRE is produced by the EPA Environmental Research Laboratory in Duluth, Minnesota. AQUIRE data are extracted from literature published worldwide and from independently compiled data files. Documents to be abstracted are identified through online literature searches, from

review article and criteria document bibliographies, and from existing aquatic toxicity reprint collections. AQUIRE includes data on acute and chronic toxicity, bioaccumulation, and sublethal effects generated from tests performed on freshwater and saltwater species. Data on aquatic mammals, birds, and bacteria are not included in AQUIRE. The data are formatted into records at the level of the individual tests or observations. Each record contains chemical substance information, test organism details, study protocol, experimental details, and results for one test or one observation within a given reference document. Thus, there can be multiple AQUIRE records for a given chemical from a single paper as well as from several different papers.

7. Phytotox: Phytotox is a database dealing with the effects of organic chemicals on terrestrial vascular plants. The database has been compiled in the Department of Botany and Microbiology at the University of Oklahoma under sponsorship of the U.S. Environmental Protection Agency. All information in the database has been extracted from open literature. Each record in the database contains information about the effects of the application of one concentration of a single chemical on a particular plant species as reported in one paper. Papers selected for inclusion in Phytotox must satisfy three principal criteria: (1) a terrestrial plant was studied; (2) organic chemicals were applied; and (3) direct effects were evaluated. Data are then extracted from these papers for inclusion in the Phytotox database. Each record in the database defines the chemical and plant species involved in the test, provides dosage and application information, lists all noted effects of the test on the plant, and provides a bibliographic citation for the source of the data.

8. Envirofate: Envirofate, developed through the collaborative efforts of EPA's Office of Toxic Substances and the Syracuse Research Corporation, contains data on approximately 800 chemicals. Envirofate contains summary information concerning the environmental fate and the physical-chemical properties of chemicals released into the environment. Chemicals selected for inclusion in the database are produced annually in excess of one million pounds. Envirofate contains twenty-four types of data extracted from papers published worldwide dealing with environmental fate and behavior studies.

Data Sources Available through TOXNET, a Division of the National Library of Medicine (NLM) -- Call 1-800-638-8480 for information on TOXNET.

9. Environmental Mutagen Information Center (EMIC): EMIC is a bibliographic database on biological and physical agents and chemicals that have been tested for genotoxic activity. EMIC covers publications from 1991 to present; earlier years are covered in EMICBACK. The files are maintained by federal funding. The database can also be searched online through the TOXNET system. URL: http://sis.nlm.nih.gov

10. Environmental Teratology Information Center (ETIC), also known as Developmental and Reproductive Toxicology Database (DART) : ETIC is a bibliographic database containing citations to publications concerning developmental and reproductive toxicology. It covers 1989 to present; earlier years are covered in ETICBACK. The files are maintained by federal funding. The database can also be searched online through the TOXNET system. URL: http://sis.nlm.nih.gov

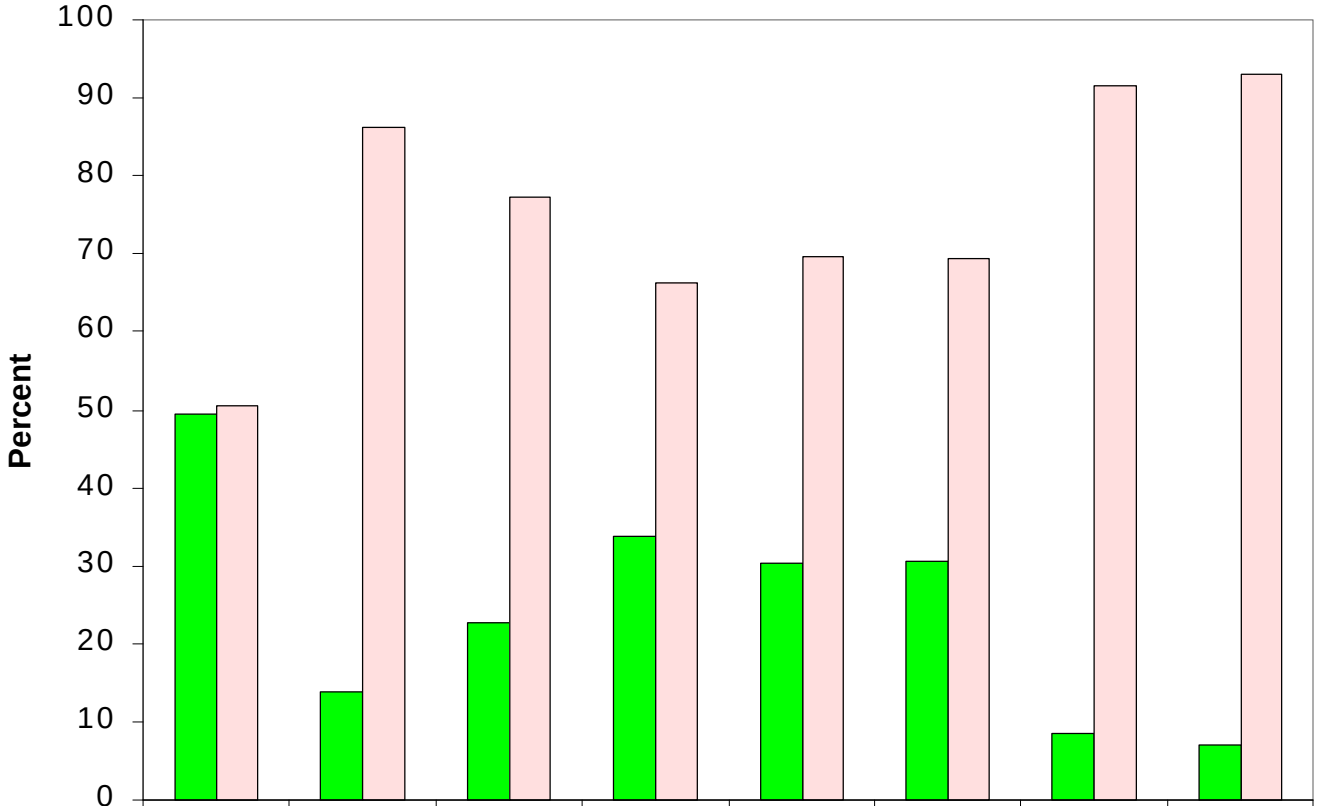
Library Reference Book

11. Shepard's Catalog of Teratogenic Agents (CTA): The CTA (8th edition) is a reference book published in 1995 by The Johns Hopkins University Press containing teratogenic information on more than 2500 chemicals. The book was authored by Thomas Shepard, and it provides a comprehensive compilation of animal and human research on the teratogenicity of chemical and environmental agents. The CTA includes many references for the Japanese as well as the American and European literature.

APPENDIX III.

Tables and Figures

Figure 1.Hazard Data Availability of Each SIDS Component for U.S. High Production Volume (HPV) Chemicals

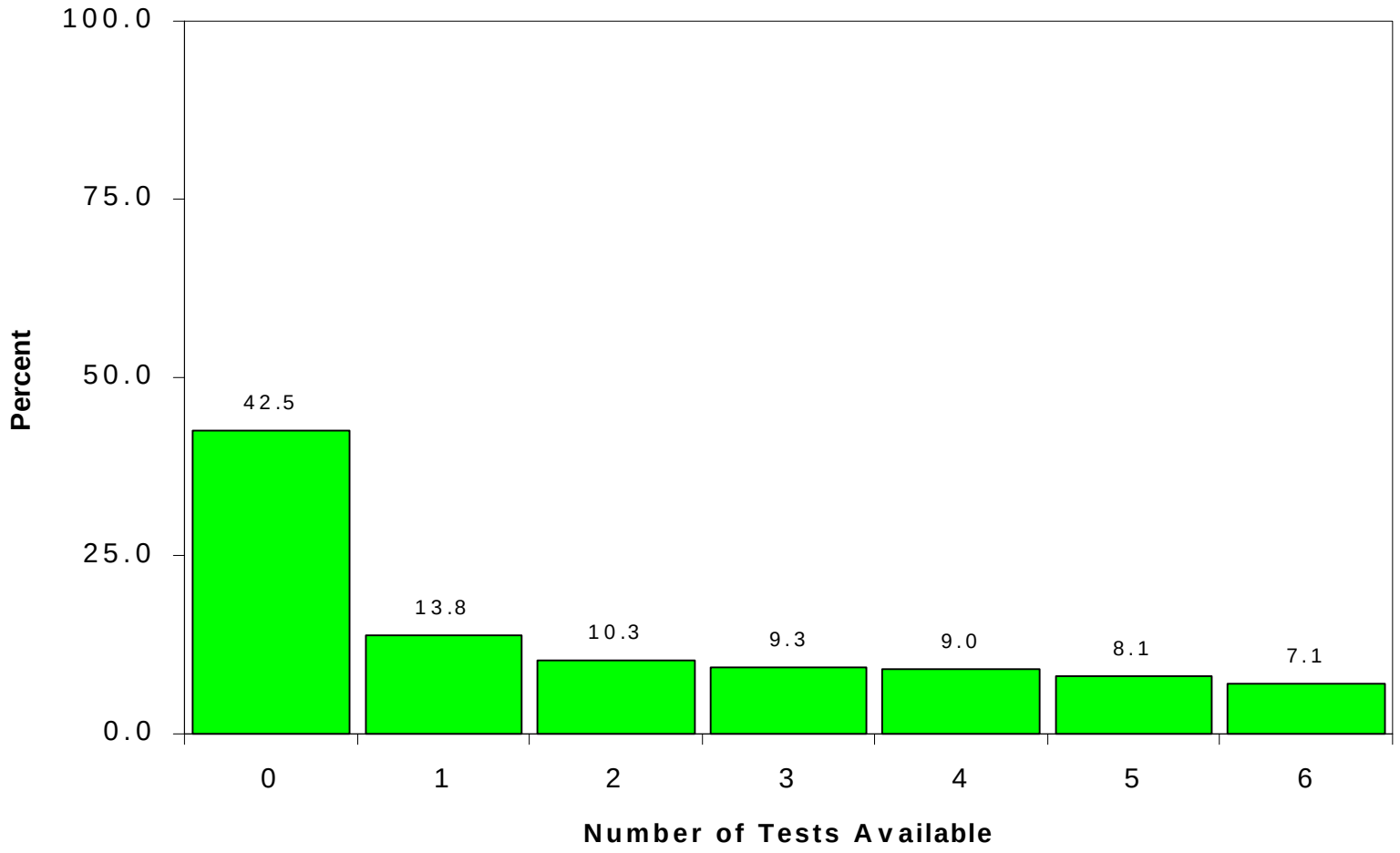


	Acute Toxicity	Chronic Toxicity	Teratogenicity/ Reproductive Toxicity	Mutagenicity	Ecotoxicity	Environmental Fate	All SIDS Health Data	All SIDS Test Data
Yes	49.4	13.9	22.8	33.8	30.4	30.6	8.5	7.1
No	50.6	86.1	77.2	66.2	69.6	69.4	91.5	92.9

Note: The six SIDS tests considered are acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate. For developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

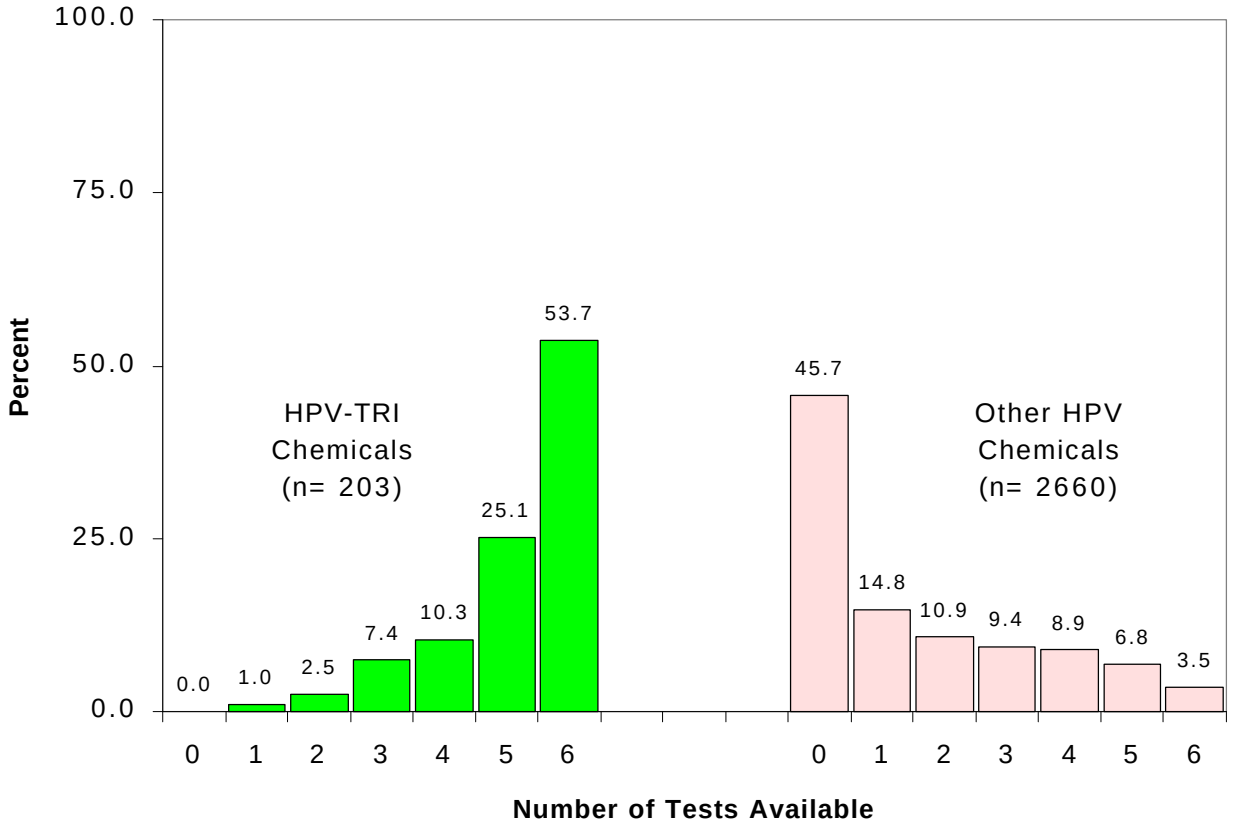
Figure 2.Hazard Data Availability for U.S. High Production Volume (HPV) Chemicals



Note: The six SIDS tests considered are acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate. For developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

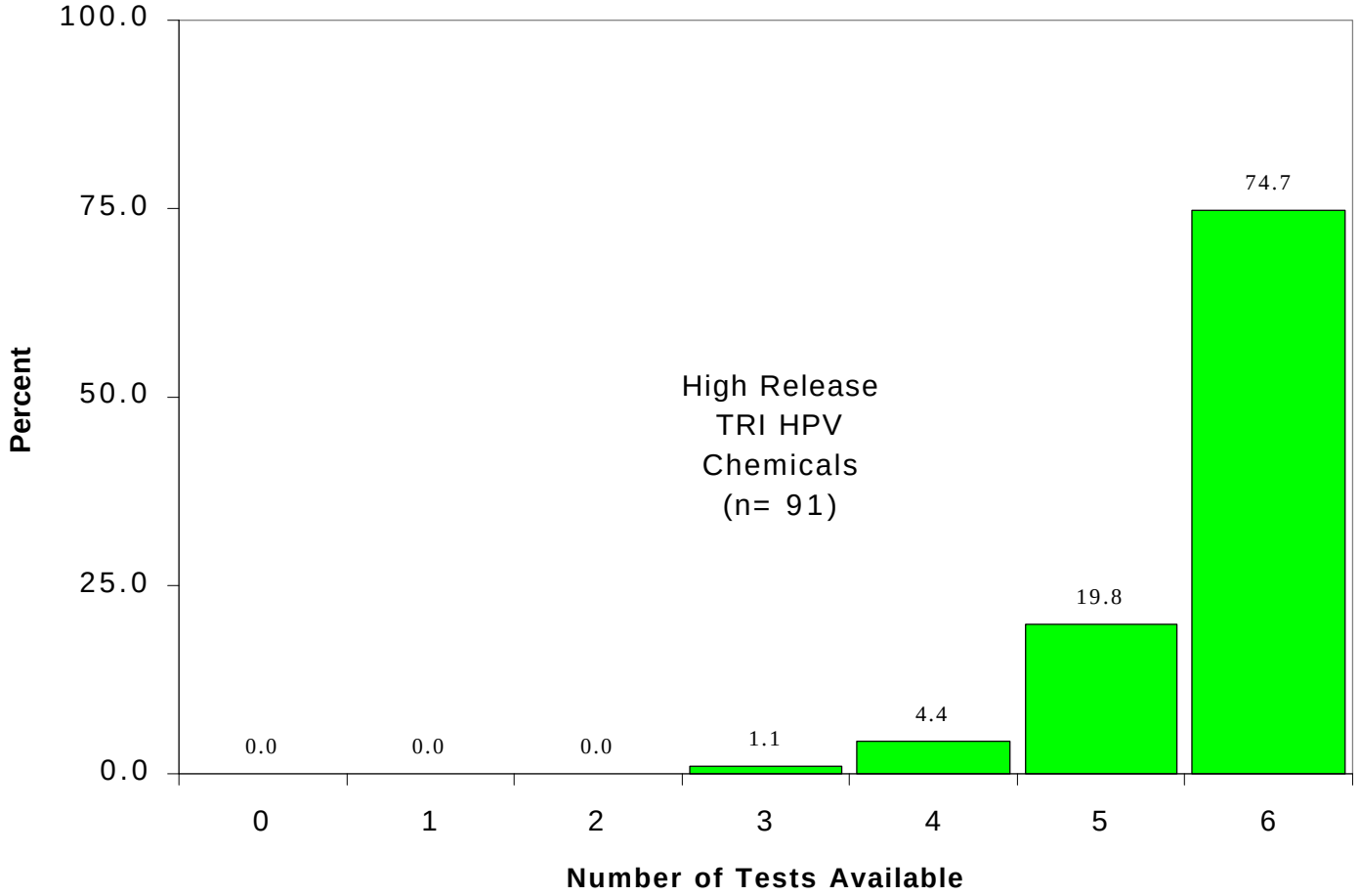
Figure 3.TRI: Hazard Data Availability for U.S. High Production Volume (HPV) TRI Chemicals



Note: The six SIDS tests considered are acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate. For developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

Figure 4.TRI: Hazard Data Availability for U.S. High Production Volume (HPV)
TRI Chemicals: Total Onsite and Offsite Releases in Excess of 1 Million Pounds[1]

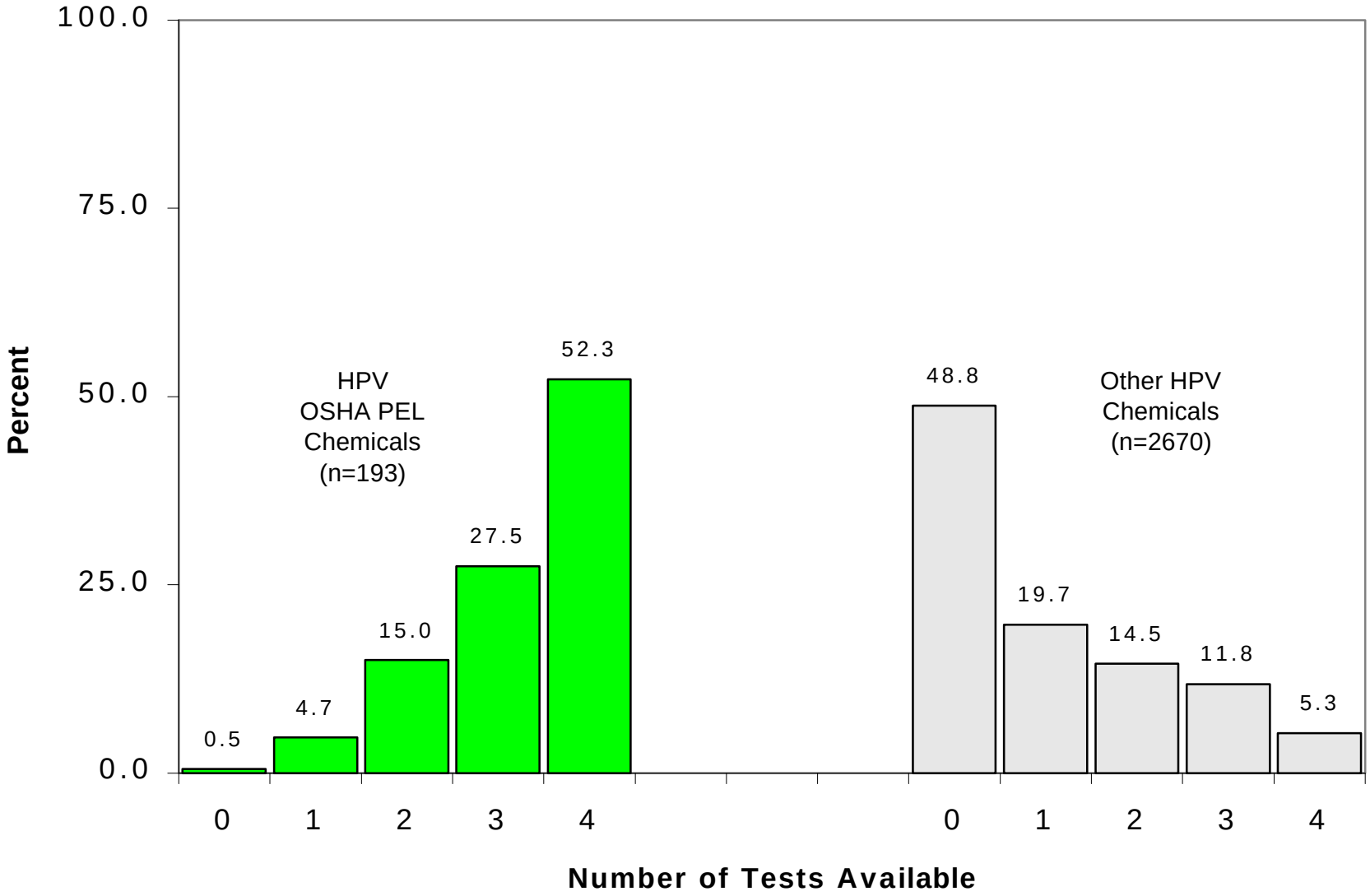


[1]Total onsite and offsite releases equals total of onsite releases and transfers to disposal.

Note: The six SIDS tests considered are acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate. For developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

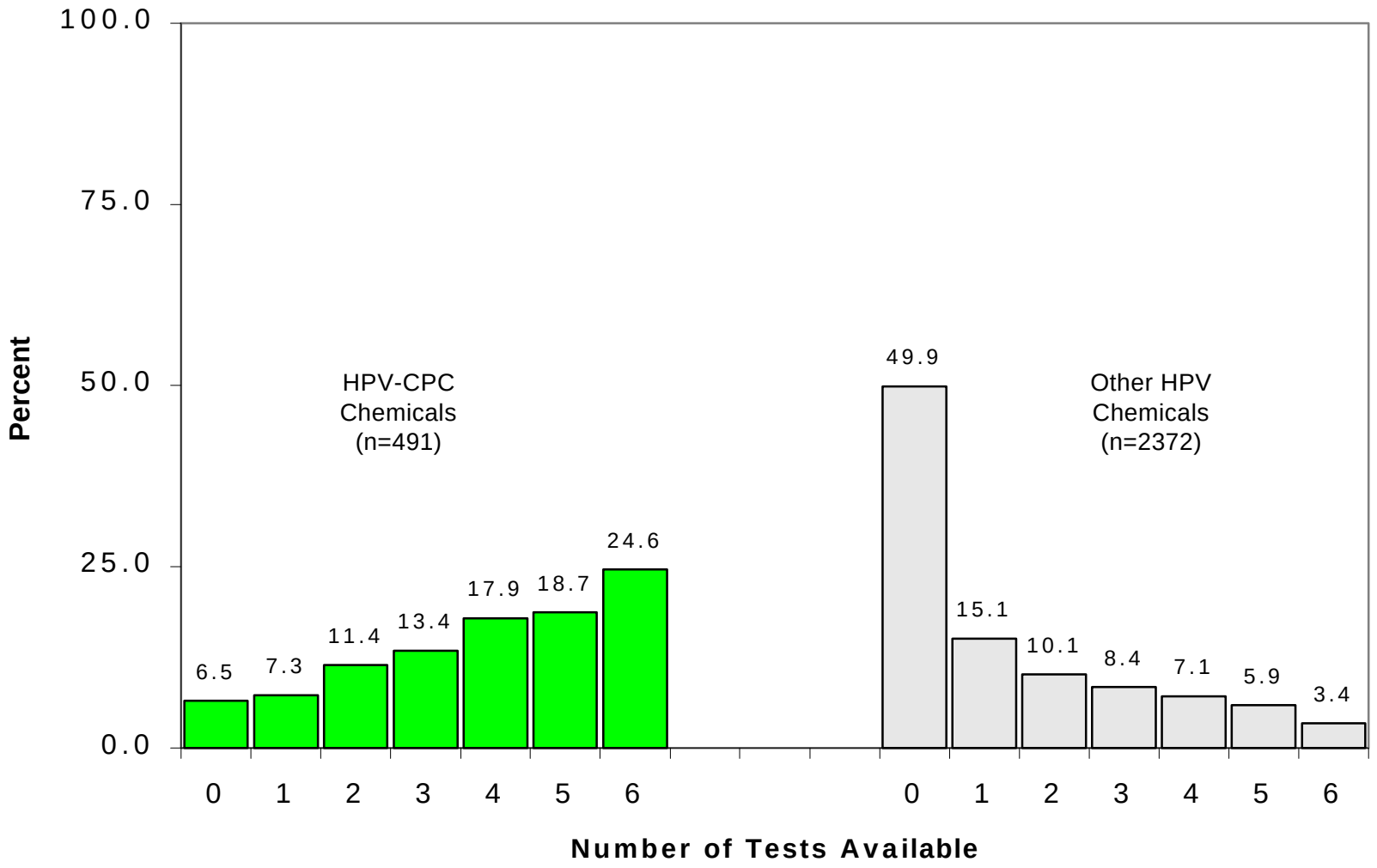
Figure 5. OSHA PEL: Hazard Data Availability for U.S. High Production Volume (HPV) OSHA PEL Chemicals



Note: The four SIDS health tests considered are acute toxicity, chronic toxicity, developmental/reproductive toxicity, and mutagenicity. For developmental/reproductive toxicity and mutagenicity, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

Figure 6.CPC: Hazard Data Availability for U.S. High Production Volume (HPV) Consumer Product Chemicals



Note: The six SIDS tests considered are acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate. For developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

Figure 7.Proportion of Hazard Data Available for 830 U.S. High Production Volume (HPV) Chemical Companies

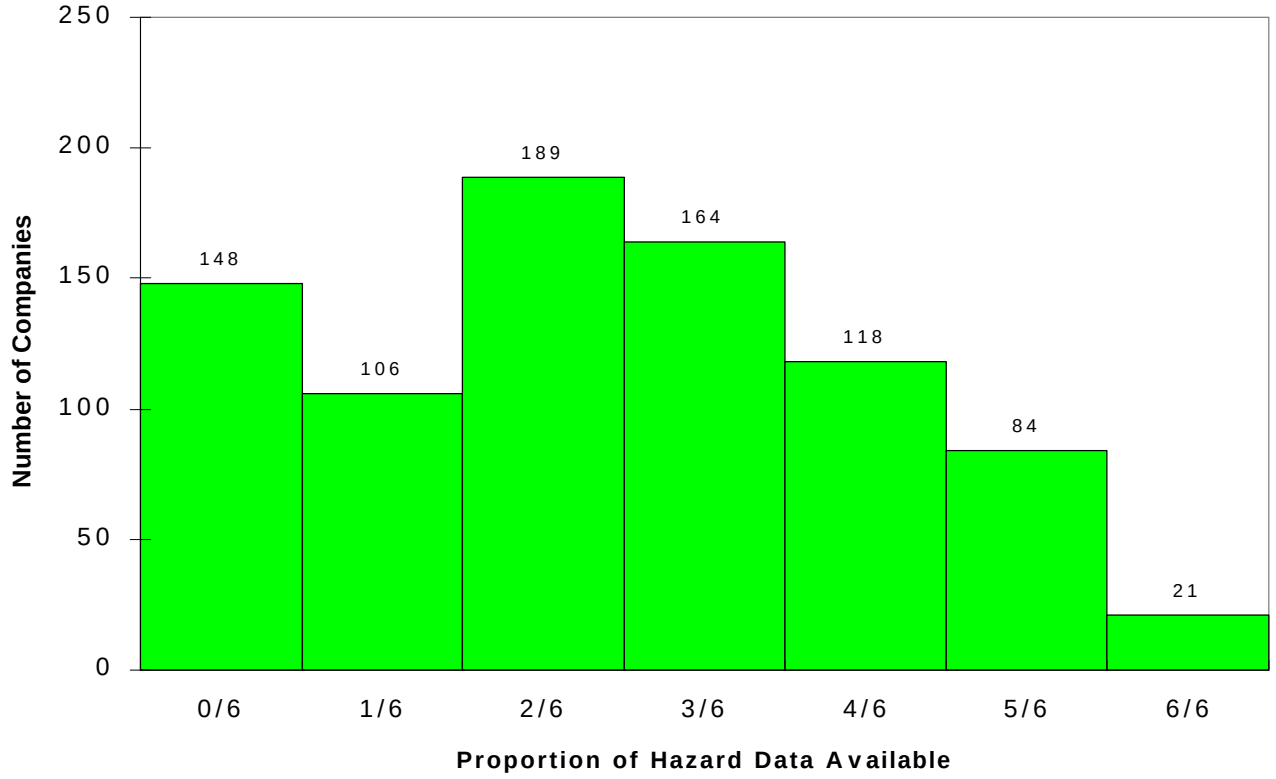


Table 1.Hazard Data Availability of Each SIDS Component
for U.S. High Production Volume (HPV) Chemicals

Test Type	Test Data Available	
	Yes	No
Acute Toxicity	1414 (49.4%)	1449
Chronic Toxicity	397 (13.9%)	2466
Developmental/Reproductive Toxicity[1]	654 (22.8%)	2209
Mutagenicity[1]	969 (33.8%)	1894
Ecotoxicity[1]	869 (30.4%)	1994
Environmental Fate[1]	877 (30.6%)	1986
SIDS Health Data[2]	242 (8.5%)	2621
All SIDS Data[3]	202 (7.1%)	2661

[1] Data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

[2] SIDS Health data include acute toxicity, chronic toxicity, developmental/reproductive toxicity, and mutagenicity.

[3] All SIDS data include SIDS Health data, ecotoxicity, and environmental fate.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

Table 2.Hazard Data Availability for U.S. High Production Volume (HPV) Chemicals

Number of SIDS Tests Performed[1]	Number of HPV Chemicals
0	1216 (42.5%)
1	395 (13.8%)
2	296 (10.3%)
3	266 (9.3%)
4	257 (9.0%)
5	231 (8.1%)
6	202 (7.1%)
TOTAL	2863

[1] SIDS test data include acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate. For developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

Table 3. Comparisons of Availability of Hazard Data for High Production Volume (HPV) Chemicals to Other Studies

Test Type	1984 NAS/NRC Study[1]	EDF 100 Chemicals		Chemical Hazard Data Availability Study[4]
		EDF Report[2] Toxic Ignorance	CMA Draft Report[3]	
Acute Toxicity	20%	>90%	99%	49%
Repeated Dose Toxicity[5] (Subchronic / Chronic)	10% (10% / 4%)	>75% (>75% / >40%)	95%	14% (Not Available / 14%)
Developmental Toxicity	6%	>55%	71%	23%[6]
Reproductive Toxicity		47%	58%	
Genetic Toxicity (In Vitro)	9%	>75%	93%	34%[6]
Genetic Toxicity (In Vivo)			71%	
Meets SIDS Requirements for Human Health[7]		29%	47%	9%

[1]Based on results of study conducted by National Academy of Sciences National Research Council in 1984 (NRC/NAS, 1984; pp.45-50) on 259 HPV chemicals randomly selected from the TSCA existing chemical inventory list (at that time, 48,523 chemicals), which underwent a standardized screening procedure to identify publicly available toxicity information (i.e., additional test data may exist in restricted access files).
[2]Chemicals with at least one test in each SIDS health category were considered to meet SIDS requirement for that category. The six SIDS health categories are acute toxicity, repeated dose toxicity, developmental toxicity, reproductive toxicity, genetic toxicity (in vitro), and genetic toxicity (in vivo).
[3]CMA, 1997.
[4]Based on EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.
[5]Test components in repeated dose toxicity testing element include subchronic toxicity testing and chronic toxicity testing.
[6]For developmental/reproductive toxicity and mutagenicity, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.
[7]For EPA's Chemical Hazard Data Availability study, SIDS human health testing includes acute toxicity, chronic toxicity, developmental/reproductive toxicity, and mutagenicity. For EDF and CMA analysis, SIDS human health data were available in each of the six toxicity endpoints listed above.

Table 4. Hazard Data Availability for U.S. High Production Volume (HPV) TRI Chemicals

Number of SIDS Tests Performed[1]	TRI Chemical	
	Yes	No
0	0 (0.0%)	1216 (45.7%)
1	2 (1.0%)	393 (14.8%)
2	5 (2.5%)	291 (10.9%)
3	15 (7.4%)	251 (9.4%)
4	21 (10.3%)	236 (8.9%)
5	51 (25.1%)	180 (6.8%)
6	109 (53.7%)	93 (3.5%)
TOTAL	**203**	**2660**

[1] SIDS test data include acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate. For developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

Table 5. TRI: Hazard Data Availability for U.S. High Production Volume (HPV) TRI Chemicals: Total Onsite and Offsite Releases in Excess of 1 Million Pounds[1]

Number of SIDS Tests Performed[2]	TRI Chemical With Total Onsite and Offsite Releases > 1,000,000 lbs
0	0 (0.0%)
1	0 (0.0%)
2	0 (0.0%)
3	1 (1.1%)
4	4 (4.4%)
5	18 (19.8%)
6	68 (74.7%)
TOTAL	91

[1] Total onsite and offsite releases equals total of onsite releases and transfers to disposal.

[2] SIDS test data include acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate. For developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

Table 6. OSHA: Hazard Data Availability for U.S. High Production Volume (HPV) OSHA PEL Chemicals

Number of SIDS Health Tests Performed[1]	OSHA PEL Chemical	
	Yes	No
0	1 (0.5%)	1303 (48.8%)
1	9 (4.7%)	526 (19.7%)
2	29 (15.0%)	386 (14.5%)
3	53 (27.5%)	314 (11.8%)
4	101 (52.3%)	141 (5.3%)
TOTAL	193	2670

[1] SIDS health test data include acute toxicity, chronic toxicity, developmental/reproductive toxicity, and mutagenicity. For developmental/reproductive toxicity and mutagenicity, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

Table 7. CPC: Hazard Data Availability for U.S. High Production Volume (HPV) Consumer Product Chemicals

Number of SIDS Tests Performed[1]	Consumer Product Chemical[3]	
	Yes	No
0	32 (6.5%)	1184 (49.9%)
1	36 (7.3%)	359 (15.1%)
2	56 (11.4%)	240 (10.1%)
3	66 (13.4%)	200 (8.4%)
4	88 (17.9%)	169 (7.1%)
5	92 (18.7%)	139 (5.9%)
6	121 (24.6%)	81 (3.4%)
TOTAL	491	2372

[1] SIDS test data include acute toxicity, chronic toxicity, developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate. For developmental/reproductive toxicity, mutagenicity, ecotoxocity, and environmental fate, test data were considered available if any studies relevant to the endpoint were located; completing the SIDS set for these endpoints requires multiple studies.

[2] As documented in EPA's 1997 Source Ranking Database.

Data Source: EPA information on 2863 U.S. HPV Chemicals from 1990 IUR Update.

Table 8. Estimated Costs for SIDS, SIDS+ and SIDS++ Testing Tiers (Based on High Production Volume/Exposure)

Level I (SIDS Battery)

OECD#	*Test Type*	*Source**	*Est. Cost*	*de novo SIDS Costs*
	Physical Chemical Properties			
102	Melting Point	CMA	$ 600	$ 600
103	Boiling Point	CMA	$ 650	$ 600
104	Vapor Pressure	CMA	$ 1,550	$ 1,550
107	n-Octanol/Water Partition Coefficient (Shake Flask)	CMA	$ 3,750	$ 3,750
105	Water Solubility	CMA	$ 3,200	$ 3,200
	Environmental Fate and Pathways			
---	Photodegradation (*Via Simple Estimation*)	CMA	$ 2,600	$ 2,600
---	Hydrolysis - Stability in Water (*Via Estimation*)	CMA	$ 3,100	$ 3,100
---	Transport/Distribution (Fugacity Model)	CMA	$ 750	$ 750
302	Inherent Biodegradation	CMA	$ 13,050	$ 13,050
	Ecotoxicity			
203	Acute Toxicity to Fish	CMA	$ 8,000	$ 8,000
202(I)	Acute Toxicity to Daphnia	CMA	$ 6,100	$ 6,100
201	Toxicity to Aquatic Plants (Algae)	CMA	$ 7,250	$ 7,250
	Mammalian Toxicity - Acute			
403	Acute Inhalation Toxicity *OR*	CMA	$ 15,900	$ 8,000 (Avg of 403, 401, 402)
401	Acute Oral Toxicity *OR*	CMA	$ 4,500	
402	Acute Dermal Toxicity (*870.1200*)	[EPA]	[$ 3,700]	
	Mammalian Toxicity - Genotoxicity			
471	Genetic Toxicity (Ames-Salmonella typhimurium)	CMA	$ 5,150	$ 5,150
473	Chromosomal Aberration (in vitro) *OR*	CMA	$ 19,500	$ 18,750 (Avg of 473 and 474)
474	Chromosomal Aberration (in vivo - micronucleus test)	CMA	$ 18,000	
	Mammalian Toxicity - Repeated Dose/Repro/Devel			
422	Combined Repeated Dose w/ Repro/Devel Tox Screen	CMA	$ 122,000	$ 122,800 (Avg of 422 & (407+415))
	OR			
407	Repeated Dose Oral Toxicity *&*	CMA	$ 60,000	
415/421	Reproductive Toxicity (1-generation)	CMA	$ 63,600	
Total				$ *205,250*

Level II (SIDS +)

SIDS Battery +	*Source**	*Est. Cost*	*Considerations*	*Total Est. Costs*
SIDS Battery (Level I) AND	**CMA**	**$ 205,000**	**[approximate figure]**	**$ 205,000**
Shake Flask Die-Away Test (*835.3170*)	**[EPA]**	**$ 33,500**		**$ 33,500**
Fish Biocentration Study (*850.1730*)	**[EPA]**	**$ 47,200**	**[flow-thru]**	**$ 47,200**
Fish Early Life Stage [static or flow-through] (*850.1400*)	**[EPA]**	**$ 40,000**	**[avg all species]**	**$ 40,000**
Daphnia Chronic Toxicity (*850.1300*)	**[EPA]**	**$ 28,200**	**[avg of static/flow-thru]**	**$ 28,200**
Avian Dietary Study in Bowhites or Mallards (*797.2050*)	**[EPA]**	**$10,000**	**[avg both species]**	**$ 10,000**
Pharmacokinetics/ADME [Tier I] (*870.7485*)	**[EPA]**	**$ 27,000**		**$ 27,000**
Acute Neurotoxicity (*798.6050-6200-6400*)	**[EPA]**	**$65,000**	**[avg all routes - rat]**	**$ 65,000**
Mouse Lymphoma Assay (*798.5300*)	**[EPA]**	**$15,000**		**$ 15,000**
Dominant Lethal Assay [rodents] (*798.5450*)	**[EPA]**	**$75,000**	**[avg all]**	**$ 75,000**
Subchronic Toxicity (*798.2250, 2450, 2650*)	**[EPA]**	**$ 125,000**	**[avg all routes - rat]**	**$ 125,000**
w/ Immunotoxicity Satellite (SRBC - PFC or ELISA)	**[EPA]**	**[TBD]**		**[TBD]**
Subchronic Neurotoxicity (*798.6050-6200-6400*)	**[EPA]**	**$ 200,000**	**[avg all routes - rat]**	**$ 200,000**
Developmental Tox (2 species) (*798.4900*) ($70,000 X 2)	**[EPA]**	**$ 140,000**	**[avg all]**	**$ 140,000**
2-Generation Reproduction Study (*870.3800*)	**[EPA]**	**$ 450,000**	**[avg all routes - rat]**	**$ 450,000**
Total				**~ $ 1,500,000 ****

Level III (SIDS++)

SIDS Battery ++	*Source*	*Est. Cost*	*Considerations*	*Total Est. Costs*
SIDS Battery + (Levels I and II) AND		**$ 1,500,000**		**$ 1,500,000**
Sediment/Water Microcosm Biodegredation	**[EPA]**	**$ 81,400**	**[avg of static/flow-thru]**	**$ 81,400**
Fish Full Life Cyle Test (*850.1500*)	**[EPA]**	**$ 250,000**	**[RAD/OPPT Est. - oral comm.]**	**$ 250,000**
Avian Reproduction Test in Mallards (*797.2150*)	**[EPA]**	**$ 66,400**	**[dietary route]**	**$ 66,400**
Pharmacokinetics (Mechanistic)	**[EPA]**	**[TBD]**	**[variable cost]**	**[TBD]**
Mouse Specific Locus Assay (*798.5195/5200*)	**[EPA]**	**$750,000**	**[avg visible/biochemical]**	**$ 750,000**
Heritable Translocation Assay (*798.5460*)	**[EPA]**	**$ 60,000**	**[avg all routes - mice]**	**$ 60,000**
Developmental Neurotoxicity (*870.6300*)	**[EPA]**	**$ 150,000**	**[avg all routes -rat]**	**$ 150,000**
Chronic/Onco [2-species (rats and mice)] (*870.4200*)	**[EPA]**	**$1,352,000**	**[avg all routes]**	**$ 1,352,000**
Total				**~ $ 4,200,000 *****

***** **CMA estimated testing costs taken from a table enclosed with a letter dated June 3,1997, from D. Helin/CMA addressed to C. Auer/CCD/OPPT/EPA with regard to a CMA proposal for an OECD/SIDS "scoring" system.**

****** **SIDS+ estimate of ~ $ 1,500,000 does not include costs for immunotoxicity satellite in the subchronic toxicity study**

******* **SIDS++ estimate of ~ $ 4,200,000 does not include pharmacokinetics testing which is both chemical case specific and variable in cost**

NOTE: **Positive effect(s) observed in lower tier test(s) would shift the chemical to higher testing tier(s) as needed.**
All EPA source cost estimates are from Economic and Policy Analysis Branch/EETD/OPPT (11/03/97 Data Cost Table and a 1998 (specific date unknown) Data Cost Table) unless otherwise specified in "Considerations"